K091363

FEB - 4 2010

510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMVDA 1990 and 21 CFR §807.92.

510(k) number:

1. Submitter's Identification:

AG Industries
3637 Scarlet Oak Blvd.
St Louis, MO 63122
USA
Submitter Phone: (866) 222-8988
Submitter Fax: (970) 494-2052
Submitter Contact: Michael Amann
Title: Vice-President
Date Summary Prepared: 1-5-2009

2. Name of the Device:

Please reference the following table for Proprietary and Common names of the devices included in this submission.

Proprietary Name	Common Name
AG1038831	Compressor Filter
LL201	Compressor Filter
LL202	Compressor Filter
LL205	Compressor Filter
HCF100	Compressor Filter
BF910 (Platinum)	Compressor Filter
BF900 (Non-Platinum)	Compressor Filter
BF950 (Patinum and Non-Platinum)	Compressor Filter
BF200C	Bacterial Filter
BF100	Bacterial Filter
BF500	Bacterial Filter
BF600	Bacterial Filter

3. Predicate Device Information:

Comparison to Predicate Devices:

The above devices are compared to similar devices marketed by Porous Media which were cleared under K061426. The features of each are exhibited in the following tables.

Feature	AG Industries	Porous Media K061426
Model	**AG1038831**	**DBF 32**
Intended Use	The filters are intended to help remove air-borne contaminants, including air borne bacteria and other particulate debris, from the air stream of a respiratory device.	Same
Filtration Efficiency	99.9+% BFE	99.999%BFE
Filter Material	Glass Microfiber	Same
Housing Material	Styrene Butadiene or approved equivalent	Polystyrene or approved equivalent
Air Flow Resistance	1.3 cm H20 @ 10 Lpm	3.0 cm H2O @ 100 scfh
Maximum Flow Rate	100 LPM	Same
Connection	12.72 mm to fit machine	22 mm ISO male/female

Feature	AG Industries	Porous Media K061426
Model	**LL205**	**DBF 27**
Intended Use	Same as AG1038831 Above	Same
Filtration Efficiency	99.99+% BFE	99.999% BFE
Filter Material	Glass Microfiber	Same
Housing Material	Styrene Butadiene or approved equivalent	Polystyrene or approved equivalent
Air Flow Resistance	.78 cm H20 @ 10 Lpm	4.0 cm H2O @ 100 scfh
Maximum Flow Rate	100 LPM	100 LPM
Connection	Male 22 mm ISO	Same

Feature	AG Industries	Porous Media K061426
Model	**LL201**	**DBF 24**
Intended Use	Same as AG1038831 Above	Same
Filtration Efficiency	99.999+% BFE	99.999%
Filter Material	Glass Microfiber	Same
Housing Material	Styrene Butadiene or approved equivalent	Polystyrene or approved equivalent
Air Flow Resistance	12.02 cm H20 @ 85 Lpm	4.0 cm H2O @ 100 scfh
Maximum Flow Rate	100 LPM	Same
Connection	Male 22 mm ISO	Same

Feature	AG Industries	Porous Media K061426
Model	**LL202**	**DBF 24**
Intended Use	Same as AG1038831 Above	Same
Filtration Efficiency	99.9+ % BFE	99.999%
Filter Material	Glass Microfiber	Same
Housing Material	Styrene Butadiene or approved equivalent	Polystyrene or approved equivalent
Air Flow Resistance	.39 cm H20 @ 10 Lpm	4.0 cm H2O @ 100 scfh
Maximum Flow Rate	100 LPM	Same
Connection	Male 22 mm ISO	Same

Feature	AG Industries	Porous Media K061426
Model	**HCF100**	**DBF 32**
Intended Use	Same as AG1038831 Above	Same
Filtration Efficiency	99.999+ % BFE	99.999%
Filter Material	Glass Microfiber	Same
Housing Material	Styrene Butadiene or approved equivalent	Polystyrene or approved equivalent
Air Flow Resistance	.33 cm H20 @ 10.5 Lpm	3.0 cm H2O @ 100 scfh
Maximum Flow Rate	100 LPM	Same
Connection	22mm ISO Male/Female	Same

Feature	AG Industries	Porous Media K061426
Model	**BF910 (Platinum)**	**DBF 25**
Intended Use	Same as AG1038831 Above	Same
Filtration Efficiency	99.99+% BFE	99.999%
Filter Material	Glass Microfiber	Same
Housing Material	Styrene Butadiene or approved equivalent	Polystyrene or approved equivalent
Air Flow Resistance	.4 cm H20 @ 5 Lpm	18 in H2O (**Platinum 10**) 7 in H2O (non-Platinum)
Maximum Flow Rate	100 LPM	Same
Connection	3/8 " FNPT and 22mm OD	3/8 " FNPT

Feature	AG Industries	Porous Media K061426
Model	**BF900 (Non-Platinum)**	**DBF 25**
Intended Use	Same as AG1038831 Above	Same
Filtration Efficiency	99.999+% BFE	99.999%
Filter Material	Glass Microfiber	Same
Housing Material	Styrene Butadiene or approved equivalent	Polystyrene or approved equivalent
Air Flow Resistance	1.6 cm H20 @ 84.9 LPM (Non-Platinum)	18 in H2O (Platinum 10) 7 in H2O (non-Platinum)
Maximum Flow Rate	100 LPM	Same
Connection	3/8" FNPT and 22mm OD	3/8" FNPT

Feature	AG Industries	Porous Media K061426
Model	**BF950 (Platinum & Non Platinum)**	**DBF 25**
Intended Use	Same as AG1038831 Above	Same
Filtration Efficiency	99.999+% BFE	99.999%
Filter Material	Glass Microfiber	Same
Housing Material	Styrene Butadiene or approved equivalent	Polystyrene or approved equivalent
Air Flow Resistance	.45 cm H20 @ 10.3 LPM	18 in H2O (Platinum 10) 7 in H2O (non-Platinum)
Maximum Flow Rate	100 LPM	Same
Connection	3/8" FNPT and 22mm OD	3/8" FNPT

Feature	AG Industries	Porous Media K061426
Model	**BF200C**	**DDF4711M03Y**
Intended Use	Same as AG1038831 Above	Same
Filtration Efficiency	99.999+% BFE	99.999%
Filter Material	Glass Microfiber	Same
Housing Material	Polypropylene or approved equivalent	Polystyrene or approved equivalent
Connection	3/8" Hose Barb	3/8" Hose Barb

Feature	AG Industries	Porous Media K061426
Model	**BF100**	**DDF4711M03Y**
Intended Use	Same as AG1038831 Above	Same
Filtration Efficiency	99.999+%	99.999%
Filter Material	Glass Microfiber	Same
Housing Material	Polypropylene or approved equivalent	Polystyrene or approved equivalent
Connection	3/16"- ¼" Stepped Bar	1/8" Hose Barb

Feature	AG Industries	Porous Media K061426
Model	**BF500**	**DDF4700M03Y**
Intended Use	Same as AG1038831 Above	Same
Filtration Efficiency	99.999+%	99.97%
Filter Material	Glass Microfiber	Same
Housing Material	Polypropylene or approved equivalent	Polystyrene or approved equivalent
Connection	¼" Straight Barb	Same

Feature	AG Industries	Porous Media K061426
Model	**BF600**	**DDF4711M03Y**
Intended Use	Same as AG1038831 Above	Same
Filtration Efficiency	99.999+%	99.999%
Filter Material	Glass Microfiber	Same
Housing Material	Polypropylene or approved equivalent	Polystyrene or approved equivalent
Connection	1/8" Hose Barb	Same

The following tests were performed to support substantial equivalence:

- Bacterial Filtration Efficiency
- Dioctyl Phthalate (DOP) Aerosol Test
- ISO Guinea Pig Maximization Test
- ISO Acute Systemic Injection Test
- MEM Elution Test
- Material Mediated Rabbit Pyrogen Test

The above tests confirmed that the performance of the subject filters is substantially equivalent to the predicate device(s). The Biocompatibility tests confirmed that the following filters BF500, BF200C, BF100 and BF600, which contain materials not in previously cleared devices, present no biocompatibility issues.

4. Device Description:

COMPRESSOR & BACTERIA FILTERS (AG1038831, LL205, LL201, LL202, HCF100, BF910, BF900, BF950, BF200C, BF100, BF500, BF600):

Room air is drawn into the compressor of a respiratory device through the bacterial intake filter. From the compress, the air passes through the Compressor Filter, if one is installed on the machine and proceeds to the sieve beds. The sieve beds condition the air by removing nitrogen from the air stream, which results in higher concentration of oxygen. The air then passes through the final filter before being supplied to the patient.

5. Intended Use:

AG Industries filters are replacement filters intended for use in oxygen concentrator machines to help remove contaminants, including air borne bacteria and other particulate

debris from an air stream. When used with oxygen concentrator machines, the replacement filters may be used in the home, nursing home, hospital, patient care facility, etc.

6. Discussion of Clinical Tests Performed:

Not applicable

7. Conclusions:

The subject devices have the same intended use and similar characteristics as the predicate devices. No new questions of safety or effectiveness are raised by differences in technology or materials. Thus, the AG Industies COMPRESSOR & BACTERIA FILTERS (AG1038831, LL205, LL201, LL202, HCF100, BF910, BF900, BF950, BF200C, BF100, BF500, BF600) are substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

FEB - 4 2010

ndd AG Industries
C/O Mr. Ian Gordon
Senior Vice-President
Emergo Group, Incorporated
1705 South Capital of Texas Highway, Suite 500
Austin, Texas 78746

Re: K091363
Trade/Device Name: Compressor & Bacteria Filters (AG1038831, LL205, LL201, LL202, HCF100, BF910, BF900, BF950, BF200C, BF100, BF500, BF600
Regulation Number: 21 CFR 868.5260
Regulation Name: Breathing Circuit Bacterial Filter
Regulatory Class: II
Product Code: CAH
Dated: January 21, 2010
Received: January 22, 2010

Dear Mr. Gordon:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/cdrh/comp/ for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number :

Device Name: COMPRESSOR & BACTERIA FILTERS (AG1038831, LL205, LL201, LL202, HCF100, BF910, BF900, BF950, BF200C, BF100, BF500, BF600):

Indications for Use:

AG Industries filters are replacement filters intended for use in oxygen concentrator machines to help remove contaminants, including air borne bacteria and other particulate debris from an air stream. When used with oxygen concentrator machines, the replacement filters may be used in the home, nursing home,hospital, patient care facility, etc.

Prescription Use ___√___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE -CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K091363